IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

MDL DOCKET No. 2816
Civil Action No. 1:18-MDL-2816

Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz,	)	**AMENDED COMPLAINT**
	)	**(Jury Trial Requested)**
Plaintiffs,	)	
	)	Judge John E. Jones, III
-versus-	)	
	)	THIS DOCUMENT RELATES TO:
Sorin Group Deutschland GMBH and Sorin Group USA, Inc.	)	*Magaly de la Cruz Gonzalez et al. v. Sorin Group Deutschland GMBH et al.*
	)	C.A. No. 2:18-CV-6248 (LAE)
Defendants.	)	

Plaintiffs, Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz, complaining of the acts of the Defendants above named, would respectfully show unto the Court as follows:

PARTIES TO THIS ACTION

1. Plaintiffs, Magaly De La Cruz Gonzalez, individually and on behalf of her minor daughter, Genesis De La Cruz, are residents and citizens of Lafourche Parish, State of Louisiana. On or about June 27, 2017, Genesis De La Cruz ("Genesis"), underwent a cardiac procedure at Children's Hospital in New Orleans, Louisiana, during which the Sorin Stockert 3T Heater-Cooler System was utilized, exposing her to Nontuberculosis Mycobacteria (NTM).

2. Upon information and belief, Defendant Sorin Group Deutschland GMBH ("Sorin") is a foreign for-profit corporation, with headquarters in Munich, Germany. Sorin

designed, manufactured and marketed the Sorin 3T Heater-Cooler System used in Genesis' surgical procedure at Children's Hospital in New Orleans, Louisiana. The Plaintiffs are under the information and belief that Sorin is the entity responsible for manufacturing the Sorin 3T Heater-Cooler Systems and distributing them to Sorin Group USA for marketing and distribution within the U.S.

3. Upon information and belief, Defendant Sorin Group USA, Inc. ("Sorin USA") is a United States designer, manufacturer, marketer, and distributor of the Sorin 3T Heater-Cooler System, with its principal place of business in Arvada, Colorado.

JURISDICTION AND VENUE

4. This Court has Personal Jurisdiction over this action pursuant to FRCP 4 and pursuant to La. R.S. § 13:3201. The Defendants are non-domiciliaries of the State of Louisiana and contract business within the State of Louisiana; the Defendants have committed tortious acts within the State of Louisiana, causing injury to persons, including the Plaintiffs, within the State of Louisiana, and said Defendants expect or should reasonably expect to have consequences in the State of Louisiana; the Defendants solicit business and engage in persistent courses of conduct and derive substantial revenue from goods used and services rendered in the State of Louisiana; the Defendants are in the business of researching, designing, developing, testing, manufacturing, distributing, licensing, labeling, and marketing, either directly or indirectly through third-party related entities, Sorin Group Stockert Heater-Cooler 3T thermal regulator devices in the State of Louisiana.

5. This Court has Subject Matter Jurisdiction over this action pursuant to 28 U.S.C. § 1332 because complete diversity exists between the parties and the amount in controversy exceeds $75,000.00.

6. Venue is proper in the Eastern District of Louisiana, pursuant to 28 U.S.C. § 1391(a)(2), because a substantial part of the events or omissions giving rise to the causes of action occurred in Louisiana and, pursuant to 28 U.S.C. § 1391(c), because Defendants are subject to Personal Jurisdiction in the Eastern District of Louisiana.

FACTUAL ALLEGATIONS

7. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

8. The Defendants manufacture, market, and sell/distribute thermal regulator devices to be used on patients in the operating room, including the Sorin 3T Heater-Cooler System ("Sorin 3T System"). Prior to June 27, 2017, the Defendants manufactured, introduced, and/or delivered for introduction into interstate commerce, the Sorin 3T System.

9. The Sorin 3T System is intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient during cardio-pulmonary bypass procedures lasting six (6) hours or less. The Sorin 3T System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510K premarket notification process ("510K" or "510K process").[1]

[1] A 510K premarket notification is a premarket submission made to the FDA to establish that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (PMA) 21 CFR 807.92(a)(3).

10. Before commercial distribution in the United States of the Sorin 3T System, Defendant Sorin submitted a 510K premarket notification of intent to market the Sorin 3T System with the Secretary of Health and Human Services for FDA approval. The FDA determined that the Sorin 3T System was substantially equivalent to legally marketed predicate devices that do not require approval of a premarket approval ("PMA") application. This determination was relayed to the Defendants via letter on June 6, 2006, 510K number K052601.[2] Essentially, the 510k process differs from the PMA process in how carefully the FDA examines the safeness of the medical device. The PMA process is required for Class III medical devices while Class I and Class II predicate medical devices can be approved through the less rigorous 510K process.

11. The FDA approval allows the Defendants to commercially distribute the Sorin 3T System in accordance with the conditions and regulations described in the approval letter. Any commercial distribution of the Sorin 3T System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act ("the Act"). Generally, the manufacturer must comply with all of the Act's requirements, including but not limited to: "Registration and Listing (21CFR part 807); Labeling (21CFR part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21CFR part 820); and if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21CFR 1000-1050."

12. On or about November 16, 2016, Children's Hospital sent out letters to certain patients that had undergone cardiac procedures wherein the Sorin 3T heart-lung machine was used, to advise the patients and their families of the potential for NTM

[2] Please see the FDA Determination Letter of Approval attached hereto as "Exhibit A".

infections to those undergoing these types of procedures. The letter indicated that the "potential for this infection is incredibly low" and that Children's Hospital would be "following all recommendations from the CDC, FDA, and the manufacturer to minimize any possible risk to patients."[3]

13. Thereafter, a second letter was sent to the Plaintiffs, personally, on August 30, 2017, to inform them that in "mid-August, 2017, several patients who underwent cardiac surgery at Children's Hospital between early June and July, 2017, developed a rare surgical site infection caused by *Mycobacterium abscessus* [(m. abscessus)]." Moreover, the letter indicated that the cause of these infections was believed to be "a piece of equipment used to regulate the temperature of patients while on bypass" and that "all suspected equipment ha[d] been removed from service and replaced."[4]

14. M. abscessus is a part of a group known as "rapidly growing mycobacteria" and is most commonly found in water, soil, and dust. If allowed within the operative field, it poses a significant health risk to surgical patients and patients that are immunodeficient.[5]

15. M. abscessus can take anywhere from weeks to years before it manifests into a non-tuberculosis mycobacterium infection.

16. Tissue that has been infected with m. abscessus usually presents as "red, warm, tender to the touch, swollen, and/or painful" and infected areas can appear as "boils." Additional signs and symptoms of the infection include "fever, chills, muscles aches, and a general feeling of illness."[6]

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[3] Please see Exhibit B attached hereto, which is a copy of the November 16, 2016 letter.
[4] Please see Exhibit C, attached hereto, which is a copy of the August 30, 2017 letter to Plaintiffs.
[5] Centers for Disease control website: http://www.cdc.gov/HAI/organisms/mycobacterium.html
[6] Id.

17. Diagnosis of m. abscessus can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the bacterium can be found in the blood and isolated from a blood sample.

18. Targeted cultures, screenings, and proper testing is usually not performed unless the physician has been made aware of this type of mycobacterium exposure. [7]

19. While death is certainly a risk of this type of infection, there are treatments available. Those include draining collections of pus or removing the infected tissue coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time. The type and period of treatment can vary greatly from patient to patient.[8]

20. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T System due to the "potential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."[9]

21. The recall instructed all affected customers to follow *new* Instructions for Use, which were outlined in the June 15, 2015 and August 6, 2015 Field Safety Notice Letters[10], issued by i.V. Christian Peis, the Director of Quality Assurance for Sorin.

22. Sorin indicated that it was providing the Field Safety Notice Letter for the following reasons:

[7] Id.
[8] Id.
[9] Please see the Recall Information from the FDA database, attached hereto as "Exhibit D."
[10] Please see the 6/15/15 and 8/6/15 Field Safety Notice Letters, attached hereto as "Exhibit E." These two letters differ in that the Operating Instructions provided in the 6/15/15 letter was intended for distribution to English speaking countries in the European Union (EU), whereas the 8/6/15 letter was intended for distribution in the U.S. Sorin claimed that while "…EU and USA cleaning and disinfection procedures are equivalent, the EU procedures include additional chemicals only available in other countries." Moreover, the U.S. Operating Instructions "…include information specific to the U.S. such as English units of measure and an Indications for Use statement."

A. [To] remind [affected users] of the importance of following the company's disinfection and maintenance procedures;

B. [To] inform [affected users] that there is a possibility that bacteria can become aerosolized when the heater cooler device is operated and serve as a source for contamination; and

C. [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.[11]

23. Upon information and belief, the Defendants knew or should have known that design and/or manufacturing defects in its Sorin 3T System made it susceptible to bacterial colonization, specifically NTM, despite any cleaning and disinfection procedures utilized.

24. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which indicated that its inspection of Sorin's Germany and Colorado facilities revealed that the Sorin 3T System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation [were] not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820."[12]

25. The FDA noted several other violations by the Defendants in the Warning Letter, which include, but are not limited to, the following:

A. Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review,

[11] Id.
[12] Please see the 12/29/15 Warning Letter, attached hereto as "Exhibit F."

and approval of design changes before their implementation, as required by 21 CFR 820.30(i);

B. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a);

C. The devices were misbranded in that Sorin failed or refused to furnish material or information respecting the device that is required by or under § 519 of the Act 21 USC § 360i and 21 CFR Part 803 – Medical Device Reporting;

D. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17;

E. Defendants' Sorin 3T System was misbranded due to its failure to notify the agency of its intent to introduce the device into commercial distribution as required by § 510(k) of the Act, 21 USC §360(k); and

F. Failure to notify the agency of significant labeling changes that affected the safety and effectiveness of the device (i.e., distributing the device with modified instructions for use with respect to the operating, maintaining, cleaning and disinfecting of the device, among other modifications).

26. Contrary to the Defendants' representations and marketing to the FDA, medical community, and to the patients themselves, Defendants' Sorin 3T System has high injury and complication rates, fails to perform as intended, requires patients to

undergo additional operations, and has caused severe and sometimes irreversible injuries, conditions, and damages to a significant number of patients, including the Plaintiffs, all of which are violations of Federal and Louisiana State rules and regulations.

27. In violation of Federal and Louisiana State requirements, the Defendants consistently under-reported and withheld information about the propensity of the Sorin 3T System to experience complications and its failure to perform as expected, has misrepresented the efficacy and safety of Defendants' System through various means and media, actively misleading the FDA, the medical community, patients, and the public at large.

28. Defendants knew, and continue to know, that its disclosures to the FDA, the public, and Plaintiffs, were, and are, incomplete and misleading and that the Sorin 3T System was and is causing numerous patients severe injuries and complications, which violates Federal and State requirements. Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, the medical community, health care providers, and patients. As a result, the Defendants actively and intentionally misled the FDA and the public, including the medical community, healthcare providers, and patients, into believing that the Sorin 3T System was safe and effective, leading to the use of Defendants' System during surgical procedures, such as the one undertaken on Genesis, as more fully described herein.

29. In violation of Federal and State rules and regulations, the Defendants failed to perform and/or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Sorin 3T System.

30. As compared to similar systems, feasible and suitable alternative designs, procedures, and instructions for use have existed at all times relevant.

31. The Defendants' 3T Sorin System was at all times relevant, utilized in a manner foreseeable to the Defendants.

32. The Defendants provided incomplete, insufficient, and misleading instructions, training, and information to hospitals and physicians, which is in direct violation of Federal and State regulations and in violation of regulations required pursuant to the 510K Approval of the Sorin 3T System in order to increase the number of hospitals and physicians utilizing the device, thereby increasing its sales.

33. The Sorin 3T System used during Genesis' surgical procedure was in the same or substantially similar condition as it was when it left the possession of the Defendants, and in the condition directed by and expected by the Defendants.

34. The injuries, conditions, and complications suffered due to the Sorin 3T System include, but are not limited to, excruciating pain, weakness, excessive additional and debilitating medical treatment, suffering, and death. Additional information that may be necessary to further establish Plaintiffs' claims will be gathered throughout the discovery process of this litigation since Plaintiffs are privy to limited supporting documentation at this time.

35. Despite Defendants' knowledge of the catastrophic injuries, conditions, and complications caused by the Sorin 3T System, in violation of Federal and State requirements, it continued to manufacture, market, provide inadequate instructions for use, and sell the Sorin 3T System, and also failed to adequately warn, label, instruct, and

disseminate information with regard to Defendants' Sorin 3T System both prior to and after the marketing and sale of the System.

FACTS SPECIFIC TO THIS CASE

36. On June 27, 2017, the Defendants' Sorin 3T System was used during Genesis' bilateral branch pulmonary arterioplasty procedure, wherein her surgeon used the device to assist in the cooling and re-warming of her blood. Genesis was subsequently discharged from Children's Hospital on or about July 2, 2017. Upon discharge, her surgical incisions were intact and healing well.

37. Thereafter, the Plaintiffs began to notice pain, swelling, and tenderness in the area of Genesis's incision site. On or about August 10, 2017, Plaintiffs relayed these issues to her pediatric cardiologist. Genesis was instructed to return to Children's Hospital for further evaluation of the sternal wound infection by her surgeon.

38. As a result of the sternal wound infection, Genesis was re-admitted to Children's Hospital on or about August 11, 2017. Upon admission, an Irrigation and Debridement procedure was performed and sternal wound cultures were obtained. She was then taken to the CICU.

39. Cultures returned with positive findings of an m. abscessus infection and a rigorous course of antibiotics were instituted, including Zyvox, Zithromax, and Amikacin. Moreover, wound vac was placed on August 13th and a peripheral IV was placed on August 17th. On or about August 29th, a left internal jugular broviac central line catheter was placed due to the need for long-term IV access.

40. Genesis remained at Children's Hospital until her discharge on or about October 10, 2017. She continued to treat with an antibiotic regimen for more than four months until early March 2018.

41. Thereafter, Genesis has continued to follow up with Infectious Disease and Cardiology for therapy and medical management.

42. As a result of the m. abscessus infection, Genesis was forced to undergo numerous additional surgical procedures, medical management, and an extensive course of antibiotic therapy that has caused numerous adverse side effects, including the possibility of future hearing loss.

COUNT I – LPLA CLAIMS FOR DESIGN DEFECTS, MANUFACTURING DEFECTS AND WARNING DEFECTS

43. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

44. The Sorin 3T System is a product within the meaning of Louisiana Products Liability Act ("LPLA"). *See* La. R.S. 9:2800.51 *et seq.* The Sorin 3T System was expected to reach, and did reach, users and/or consumers, including the Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was sold or distributed. At all times material and relevant, the Sorin 3T System was used in a manner intended and/or foreseeable to the Defendants for the purposes of heating and cooling patient blood during major cardiac procedures and was so used by this Plaintiff for those purposes of which it was marketed, advertised, promoted, and instructed to be used, including cardiac procedures.

45. A patient or consumer utilizing the Sorin 3T System would reasonably expect the device to be free of significant defects. The Sorin 3T System, as designed by

the Defendants, colonizes NTM and directly transmits that bacteria to the patient during invasive surgical procedures.

46. The Defendants' intended design and intended manufacturing process for the Sorin 3T System did not include a product contaminated with NTM in the production at Defendants' facilities or through the devices foreseeable and intended use; however, the device did become contaminated with NTM, including the one used during Genesis' procedure, during the manufacturing process and/or through foreseeable and intended use in accordance to the Defendants' instructions, specifically, m. abscessus, and therefore the device deviated in a material way from the Defendants' specifications or performance standards for the Sorin 3T System, at the time it left the Defendants' control, making it defective and unreasonably dangerous in construction and composition.

47. The foreseeable risks of using the Sorin 3T System as designed and instructed significantly outweighs the benefits, and, at the time the Sorin 3T System left Defendants' control, safer, more practical, feasible, and otherwise reasonable alternative designs existed and could have been adopted for the device which would have prevented or substantially reduced the risk of harm (i.e., bacterial colonization and transmission thereof through aerosolization) to the patients, including Genesis, without substantially impairing the usefulness of the device. The risk and gravity of that harm clearly outweighed the burden on the Defendants of implementing such alternative design. Reasonable alternative designs included, but are not limited to, measures to ensure the vent and consequential airflow did not create a direct path for NTM to travel into the patient's surgical field, measures to allow for easier disinfection, measures to prevent biofilm formation (i.e., disposable liners, etc.), internal features to prevent colonization of

bacteria formation, technology aimed at reducing bacterial contamination within the unit, and/or measures to provide some type of protection, barrier and/or enclosure on or around the exhaust vent or even the unit itself.

48. Defendants' failure to use feasible and reasonable alternative designs that would eliminate bacterial colonization (including the colonization of NTM) and aerosolization of that bacteria into the surgical field of patients undergoing cardiac procedures, make the Sorin 3T System unreasonably dangerous and defective and unreasonably unsafe for its intended purpose.

49. Had Plaintiffs or any other reasonable similarly situated person known of the unreasonableness of the Sorin 3T System and its unsafe design as described herein, they would not have utilized the device during the cardiac procedure.

50. Defendants knew or should have known that the Sorin 3T System, as designed, could cause NTM to colonize within the system and cause contamination to patients during invasive cardiac procedures through the device's exhaust vent as early as 2002, and certainly, between the time of sale of the device and the time that it was used during Genesis' procedure. However, the Defendants did not adequately warn patients or users of the risk of NTM colonization within the Sorin 3T System and its propensity to aerosolize through the exhaust vent into the patient's surgical field, nor did the Defendants adequately instruct users of the Sorin 3T System on the proper cleaning and disinfection procedures to prevent such colonization and aerosolization.

51. The Sorin 3T System utilized during Genesis' surgery was sold without adequate warnings or instructions for use, which rendered the device unreasonably dangerous and defective and it posed a substantial risk of harm to Genesis and any

reasonably foreseeable patients.

52. The Defendants owed a duty of reasonable care to the general public, including the Plaintiffs, when it designed, labeled, manufactured, assembled, inspected, tested, marketed, advertised, promoted, and placed/distributed into the stream of commerce, instructed, and sold the Sorin 3T System, to assure that the product was in compliance with FDA regulations and not defective and/or unreasonably dangerous for its intended purposes and foreseeable uses.

53. The Defendants breached this duty by designing, labeling, manufacturing, assembling, inspecting, testing, marketing, advertising, promoting, distributing, instructing, and selling/distributing the Sorin 3T System in an unreasonably dangerous, defective and unreasonably unsafe condition including, but not limited to, its propensity for the colonization of organisms, including NTM, and the transmission of that bacteria to patients undergoing invasive surgical procedures.

54. The Defendants owed Plaintiffs a duty of reasonable care to discover defects and/or errors in the machine and to inform and/or warn the FDA and Plaintiffs of a defect once it was discovered. The Defendants violated these duties when it failed to do so, which further placed the Plaintiffs at risk for harm and injury.

55. The Sorin 3T System differed in design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising from the System that received approval through the 510K process, and thus the design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising of the Sorin 3T System used at Children’s Hospital during Genesis’ cardiac procedure was done so in violation of those requirements.

56. The Defendants had the duty to comply with and not deviate from statutory requirements, which amongst other things, require that the device be manufactured, labeled, and designed according to the standards laid out in the FDA approval. The Defendants violated these duties when it failed to comply therewith and distributed a device that deviated from the statutory requirements.

57. As a direct and proximate result of Defendants' violations, the Plaintiffs have suffered severe debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost enjoyment of life, lost income, mental anguish and emotional distress, scarring, and pain and suffering, all of which are continuous in nature.

58. As the manufacturer of the unreasonably dangerous and defective Sorin 3T System, the Defendants are liable to the Plaintiffs for their damages proximately caused by the Sorin 3T System, pursuant to the LPLA, because such damage arose from a reasonably anticipated use of the Sorin 3T System during Genesis' surgery.

COUNT II - BREACH OF EXPRESS WARRANTY UNDER LPLA

59. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

60. The Defendants warranted, both expressly and impliedly, through its marketing, advertising, distributors and sales representatives, that the Sorin 3T System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

61. The Defendants are aware that health care providers and patients, including Genesis, rely upon the representations made by the Defendants when

choosing, selecting, and purchasing its products, including the Sorin 3T System, which was relied upon by these Plaintiffs. Indeed, the express and implied warranties made by the Defendants about the Sorin 3T System induced Children's Hospital to use the Sorin 3T System.

62. As previously discussed and further identified herein, due to the defective and unreasonably dangerous design, labeling, manufacturing, and distribution of the Sorin 3T System, which was in violation of statutory requirements and regulations, the product was neither of merchantable quality, nor fit for the ordinary purposes for which it was sold, presenting an unreasonable risk of injury to patients, including Genesis, during foreseeable use.

63. The Defendants' violations of Federal and State statutory rules and regulations and the defective and unreasonably dangerous condition of the Sorin 3T System constituted a breach of the Defendants' express and implied warranties, and such breaches were a direct and proximate cause of the incident and damages described herein, and for which Plaintiffs are entitled to compensatory and punitive damages in an amount to be proven at trial.

COUNT III – LUTPA CLAIM

64. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

65. At all times relevant to this action, the Louisiana Unfair Trade Practices and Consumer Protection Law ("LUTPA"), codified at La. R.S. 51:1401 *et seq.*, was in effect. LUTPA provides, in pertinent part, that: "Unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce are declared

unlawful." La. R.S. 51:1405(A).

66. The Defendants have engaged in deceptive acts or practices in violation of the LUTPA, including but not limited to, utilizing deception, fraud, misrepresentation, concealment, omission, and suppression of research from investigations, adverse events reported to the FDA, and clinical trials regarding the safety, efficacy, instructions for use, and the unreasonably dangerous nature of the Sorin 3T System.

67. The Defendants violated the LUTPA by concealing, omitting, and failing to inform the FDA, the Plaintiffs, the medical community, and other purchasers of the failures, adverse reactions, complications, and the insufficiency of the Instructions For Use as it related to the Sorin 3T System.

68. Defendants' deceptive acts and practices occurred during a course of conduct involving trade or commerce.

69. As a direct and proximate cause of the Defendants' violations of Federal requirements and LUTPA, the Plaintiffs have sustained, severe physical and emotional injuries and ascertainable economic loss, which are continuous in nature, for which Plaintiffs are entitled to attorney's fees and compensatory and treble damages in an amount to be proven at trial.

ACTUAL DAMAGES

70. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

71. As a direct and proximate result of the acts, omissions, and violations of the Defendants alleged herein, the Plaintiffs suffered injuries and damages. The injuries and damages for which Plaintiffs seek compensation from the Defendants include, but are not

limited to:

a. physical pain and suffering of a past, present and future nature;

b. emotional pain and suffering of a past, present and future nature;

c. permanent impairment and scarring;

d. medical bills and expenses of a past, present and future nature;

e. loss of past and future lost wages and loss of earning capacity;

f. loss of enjoyment of life;

g. pre- and post-judgment interest;

h. statutory and discretionary costs; and

i. any and all such further relief, both general and specific, to which they may be entitled to under the premises.

JURY DEMAND

72. Plaintiff demands a trial by jury on all issues, pursuant to Rule 38 of the Federal Rules of Civil Procedure.

PRAYER FOR RELIEF

73. The Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation in this Complaint.

74. **WHEREFORE, PREMISES CONSIDERED,** the Plaintiffs bring this Complaint against the Defendants for personal injuries and pray for a judgment against the Defendants for compensatory damages, in an amount considered fair and reasonable by a jury and for all such further relief, both general and specific, to which Plaintiffs may be entitled under the premises.

Respectfully submitted,

PLOTKIN, VINCENT & JAFFE, L.L.C.

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Pro Hac Vice Motion Forthcoming

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